Question and Answer Supplement for Response to Preproposal Statement of Inquiry (WSR 02-05-054) by Interagency Regulatory Analysis Committee Pharmaceutical Workgroup

Who is the IRAC Pharmaceutical Workgroup?

The Interagency Regulatory Analysis Committee (IRAC) is composed of more than 350 members from 160 regulatory agencies in Washington State and is staffed by the Local Hazardous Waste Management Program in King County. IRAC encourages and addresses regulatory coordination and interagency cooperation and provides a forum for agencies to work together to address regulatory issues, conflicts and inconsistencies. Issue-specific workgroups are formed to study the circumstances around a conflict or inconsistency and the needs of all involved parties and to recommend improvements or changes in local ordinances or state or national regulations.

Questions relating to the proper disposal and recycling of pharmaceutical wastes in Washington were brought to IRAC by the Medical Industry Roundtable (MIRT). In March 2001 IRAC formed a Pharmaceutical Workgroup to address these issues and make recommendations.

The IRAC Pharmaceutical Workgroup is comprised of representatives from the pharmaceutical industry, reverse distribution businesses, non-profit organizations, educational institutions and regulators. For a complete list of participants, see the signature page of the attached letter.

What has precipitated the proposed rule change?

In response to a citizen's inquiry in May 2001, the Washington State Department of Ecology (Ecology) determined that some expired and unusable pharmaceuticals designated as Washington state-only dangerous wastes. With that determination, the entire management process then in place for handling expired and unusable pharmaceuticals was brought to a halt. Wastes should be handled properly. Unfortunately, the process to identify and designate pharmaceuticals as state-only dangerous waste is a burdensome, overwhelming and virtually impossible task. Therefore, the proposed rule change creates conditions under which these wastes could be conditionally excluded from regulation as state-only dangerous waste and still be properly managed.

After a review of the entire pharmaceutical distribution process—from drug development to final destruction—the Pharmaceutical Workgroup determined that the dangerous waste management system, created primarily for industrial process waste, is not well suited for managing expired and unusable drugs generated in health care settings. A reliable method of designating drugs as dangerous waste based on available information has not been developed. In addition, it was stated by Department of Ecology spokeswoman Caitlin Cormier, in the Thursday, January 24, 2002 **Spokesman-Review** article *Drugs pile up; incinerator can't take them* written by Dan Hansen, that, "the agency never intended to classify drugs as a hazardous waste." (See http://www.spokesmanreview.com/news-story.asp?date=012402&ID=s1090288.)

In order to facilitate the proper reuse, recycling and disposal of pharmaceuticals, and to provide information and education to generators of this waste, change is needed. In January 2002, Ecology passed an emergency rule (WSR: 02-05-030) that excludes law enforcement agencies in possession of DEA-regulated controlled substances from the provisions of the Dangerous Waste regulations when certain disposal conditions are met. The Pharmaceutical Workgroup would like to expand and clarify the provisions of this emergency rule and make it permanent.

The ultimate goal of the Workgroup is to provide regulators in the state of Washington with a regulatory framework that provides for the proper management of this wastestream and that addresses the needs of generators.

What is Ecology being asked to do?

The Pharmaceutical Workgroup has requested that Ecology phrase the permanent rule (WSR:02-05-054) currently under consideration to conditionally exclude pharmaceuticals from the dangerous waste regulations to read as follows:

> Drugs regulated by the Drug Enforcement Administration (DEA) Schedules I through V that are held by any licensee or registrant of the state authorized to possess these drugs or that are held in the custody of law enforcement agencies within the state of Washington; and drugs as defined by Section 201 (g) of the Federal Food, Drug and Cosmetic Act (excluding compressed gases and radioactive drug products); and managed for destruction: Provided, that they are disposed of by incineration in a controlled combustion unit permitted to handle solid waste or disposed by other methods approved by Ecology.

The Dangerous Waste regulations at WAC 173-303-071(2) state that "No waste class will be excluded if any of the wastes in the class are regulated as hazardous waste under 40 CFR Part 261." Therefore, the proposed language is limited to excluding state-only dangerous wastes.

What does the proposed language do?

The emergency rule (WSR: 02-04-030) passed by Ecology on January 25, 2002 to address this issue allows an exclusion only for law enforcement agencies in possession of DEA-regulated controlled substances. To ensure that the wastestream of controlled substances is handled consistently, regardless of the generator, this proposal includes DEA registrants such as doctors, hospitals, pharmacies, etc. The language change proposed above clarifies the scope of the waste and includes other generators of this waste in addition to law enforcement agencies.

- Scope of the Waste: The conditional exclusion proposed above acknowledges the similarities in toxicity, volume and generation of DEA-regulated controlled substances, pharmaceuticals and over-the-counter drugs; while the original emergency rule addressed DEA-regulated controlled substances alone.
- Scope of the generators: The original emergency rule addressed only law enforcement agencies. The conditional exclusion proposed above addresses all generators.

What types of businesses are faced with managing expired and unusable pharmaceuticals?

The emergency rule addresses only law enforcement agencies. The conditional exclusion proposed above expands the scope to include other businesses faced with managing controlled substances and other pharmaceuticals.

Issues with managing expired and unusable pharmaceuticals are encountered by thousands of businesses ranging from large hospital generators to very small businesses. They include nursing home facilities, veterinarians, missionary organizations, medical centers, fire stations, hospices, doctor's offices, adult daycare centers, dentists, ambulance services, and correctional facilities, to name a few.

How are most unusable or expired pharmaceuticals currently managed?

Most unusable or expired pharmaceuticals are sent to *reverse distributors* who facilitate their return to the manufacturer. This system allows unusable or expired pharmaceuticals to flow back through the reverse distribution system as *products* until a decision is made to discard them by the reverse distributor. At the reverse distributor, about 70 percent of a typical shipment received will be returned to the manufacturer for credit and the remaining 30 percent will designate as either hazardous or nonhazardous waste based on federal Resource Conservation and Recovery (RCRA) regulations. Of the items being discarded (30 percent of the original shipment), only about 10 percent (or three percent of the original shipment) typically designates as hazardous waste under RCRA, which must be managed as regulated hazardous waste and is not eligible for the conditional exclusion proposed above.

The reverse distributor is responsible for properly storing, manifesting, and arranging for transport and disposal of the hazardous waste by a federally permitted RCRA incineration facility. The nonhazardous waste must be disposed of by a facility permitted to destroy nonhazardous pharmaceutical waste.

How are pharmaceuticals that are not processed by a reverse distributor managed?

Lack of generator knowledge about proper disposal requirements is reflected in the many disposal methods used for pharmaceuticals that are not returned to a reverse distributor. Prior to May 2001, some pharmaceutical wastes were managed as solid waste and incinerated by high-temperature combustion at the Spokane Waste-to-Energy facility. The Spokane Waste-to-Energy facility is not permitted to handle dangerous wastes, and stopped this practice pending review. As of January 25, 2002 the facility began to accept shipments of controlled substances excluded from the Dangerous Waste regulations by the emergency rule (WSR 02-04-030).

Some chemotherapy wastes are disposed through permitted hazardous waste treatment, storage, and disposal companies. Finally, a small percentage of non-returned pharmaceuticals is being improperly disposed as biohazardous waste, solid waste or put down the drain to the sewer.

Workgroup participants representing solid waste and sanitary sewer interests reported that they do not approve disposal of pharmaceuticals into their systems. Examples include:

- partially filled chemotherapy bags specially blended for patients who are too ill to receive them or have died
- partial doses of injections
- individual tablets or capsules that have spilled and then been swept into the garbage.

How will conditional exclusion improve the disposal practices of hospitals, pharmacies, doctor's offices, etc.?

With the conditional exclusion of expired and unusable pharmaceuticals from the state-only portion of the Washington State Dangerous Waste regulations, regulators will have feasible and practical guidelines to give to pharmaceutical waste generators. Currently, regulators must tell generators to examine each pharmaceutical for dangerous waste characteristics and criteria. Due to a lack of toxicity data and the general complexity of drugs, regulators as well as generators are overwhelmed with the task of book designating more than 10,000 pharmaceuticals currently on the market.

In order for a waste disposal program to be effective, health care industry staff need clear procedures for how to deal with any wastestream. For example, a nurse caring for six cancer patients on a night shift may, within the course of an hour, generate a half-full IV bag of chemotherapy medication, spilled pills, and an unused dose of injectable pharmaceutical. It is unreasonable to expect him or her to designate and segregate each waste before placing it into a waste receptacle. Since reverse distributors cannot accept wastes like those described in this example—e.g., out of the container or modified for specific patients—the most practical and safe solution is to place state-only pharmaceutical waste into a single receptacle designated for incineration by high-temperature combustion (or another Ecology-approved disposal method.) This is clear guidance a regulator could give to professional healthcare or other personnel in health care settings.

How will Washington State businesses be impacted if pharmaceutical wastes are not conditionally excluded from state-only dangerous waste?

The Washington State Dangerous Waste Regulations create an unfair competitive advantage for out-of-state businesses that manage pharmaceutical wastes. Any United States hospital, retail pharmacy or drug distributor can send their unopened, unneeded or expired pharmaceuticals to a reverse distributor. There is no reverse distribution system available to medical doctors, dentists, veterinarians and other types of non-pharmacy dispensers. Only pharmacies and their drug distributors have the manufacturer credit policies available to them. Expired drugs generated at these other sites would become waste.

Upon receipt of the unused pharmaceutical, the reverse distributor decides if it can be returned to the manufacturer for credit or if it is waste. Because the reverse distributor designates the waste, the hazardous waste laws of the state where the reverse distributor is located apply. The majority of large hospitals and pharmacies use these reverse distributors to handle much of their expired

or unusable pharmaceuticals. However, most of the reverse distributors are located in states in which only federal RCRA regulations apply to pharmaceutical waste. Because pharmaceutical waste in our state is also subject to state-only dangerous waste regulations, Washington State reverse distributors are at a great competitive disadvantage. The costs to dispose of unusable pharmaceuticals are currently significantly higher in Washington State than, for example, in New Jersey. It is less expensive because Washington criteria are not applied in New Jersey and therefore the wastes are not managed as dangerous. Excluding unusable pharmaceuticals from designation as Washington state-only dangerous waste would put Washington State reverse distributors on par with those operating in other states.

Why should waste pharmaceuticals be conditionally excluded from state-only dangerous waste criteria when other wastes are not?

Unusable and expired pharmaceuticals do not fit within the system used to determine if a waste is a state-only dangerous waste. The Dangerous Waste regulations do not allow for the differences between FDA-regulated chemicals intended for human or animal consumption and chemicals intended for use in industrial processes. Further, according to the previously cited statement by Caitlin Cormier of Ecology in the **Spokesman-Review**, the Dangerous Waste Regulations never intended to regulate pharmaceuticals.

To determine if a product is hazardous waste under the state-only criteria of Washington State Dangerous Waste regulations, one must have specific toxicity data as defined by the Washington State Dangerous Waste regulations for the product or chemical. This information does not exist for many pharmaceuticals because the manufacturers of pharmaceuticals are regulated under the Food and Drug Administration (FDA). Until May 2001 most generators were not aware that pharmaceuticals fell under the purview of the Washington State Dangerous Waste Regulations. Although the FDA requires extensive testing prior to the release new pharmaceuticals, this does not typically include acute toxicity testing by the methods needed for state toxicity designation (e.g., lethal concentrations in water for fish, oral rat lethal doses, inhalation rat lethal concentrations in air, or dermal rabbit lethal doses).

Another way to determine if a waste is a Washington state-only dangerous waste is to conduct bioassays. These tests are extremely expensive. Because drug formulations are continually modified, new bioassays would have to be conducted continually, with each reformulation. This is a prohibitive and arduous undertaking.

Do pharmaceuticals included within the proposed changes meet the criteria required for an excluded category of waste?

WAC 173-303-071 excludes certain categories of waste from the provisions of the dangerous waste regulations “because they generally are not dangerous waste, are regulated under other state and federal programs, or are recycled in ways which do not threaten the public health or the environment.”

"…because they … are regulated under other state and federal programs…"

- The Environmental Protection Agency (EPA) regulates wastes designated as hazardous under the Resource Conservation and Recovery Act (RCRA).
- The Drug Enforcement Administration (DEA) regulates the manufacture, transport and destruction of pharmaceuticals that are Controlled Substances, Schedules I, II, III, IV and V as outlined in the 21 CFR 1300.01 Definitions relating to Controlled Substances, and 1308.03 – 1308.15 Administration Controlled Substance Code Number.
- The Food and Drug Administration (FDA) promotes and protects the public health by helping safe and effective products reach the market in a timely way and monitoring products for continued safety once in use.
- The Washington Board of Pharmacy regulates pharmaceuticals as outlined in the Washington State Department of Health, Board of Pharmacy, Pharmacy Lawbook, Chapter 69.50 RCW Uniform Controlled Substances Act, Chapter 69.41 RCW Legend Drugs-Prescription Drugs, and Chapter 69.60 RCW Over-The-Counter Medications.
- The federal Prescription Drug Marketing Act (PDMA) regulates management of the return of expired or unusable pharmaceuticals to the manufacturers.
- The Washington State Department of Health has delegated authority from the Nuclear Regulatory Commission to enforce regulations pertaining to nuclear energy and radiation under Chapter 70.98 RCW with implementing regulations found in Chapters 246-221, 246-231, 246-232, 246-235, 246-239, and 246-249 WAC. The Washington State Department of Ecology regulates radioactive wastes under Chapters 173-44, 173-325, 173-326, and 173-328 WAC.

Under the conditional exclusion proposed above, the Dangerous Waste Regulations (Chapter 173-303) continues to regulate unusable and expired pharmaceuticals so that they are reused or disposed in accordance with federal, state and local regulations. The conditional exclusion ensures that pharmaceuticals regulated as Washington State-only dangerous wastes are disposed in a way that prevents their release to the environment. Any pharmaceutical regulated as waste under 40 CFR Part 261 may not be excluded.

"… because they … are recycled in ways which do not threaten the public health or the environment…"

As a result of the Prescription Drug Marketing Act (PDMA), the reverse distribution system now addresses the recycling and reuse of unused and expired pharmaceuticals.

Additionally, the proposed language provides that drugs not accepted in the reverse distribution system undergo high-temperature combustion in Spokane's Waste-to-Energy facility (recycling for energy recovery).

How are pharmaceuticals regulated under other state and federal programs?

Environmental Protection Agency (EPA)

Pharmaceuticals regulated under the federal Environmental Protection Agency (EPA) hazardous waste regulations, the Resource Conservation and Recovery Act (RCRA), must be disposed of at a permitted hazardous waste facility. RCRA regulates drugs that are ignitable, reactive, or hazardous compressed gases. Wastes containing hazardous levels of certain toxic chemicals (eg., barium, mercury, silver and cresol) are also regulated by RCRA. Some drugs contain active ingredients listed as hazardous discarded chemical products on the RCRA U and P lists. The State of Florida has compiled a fact sheet on regulation of pharmaceuticals that provides examples of federally regulated pharmaceutical wastes (attached). See http://www.floridacenter.org/brochures_bulletins/rcra_pharmacies.pdf for the complete fact sheet. *The proposed exclusion makes no change in how these materials are handled.*

The Drug Enforcement Administration (DEA)

The DEA tracks controlled substances through their life cycles—from raw material through the manufacturing process to the pharmacy and ultimately to the patient or to the substance's destruction. DEA can track a single tablet from its manufacture to its ultimate fate. DEA strictly regulates destruction of controlled substances, licensing some people to witness the destruction of controlled substances on its behalf. About ten percent of pharmaceuticals fall into one of five "schedules" under the category of controlled substances. Each schedule requires a different level of reporting. The DEA enforces a closed system of distribution.

The Food and Drug Administration (FDA)

Since 1938 FDA has approved new drugs used for humans or animals for safety. Drug efficacy was added to the approval process in 1962. Drugs already on the market prior to these dates are not typically reviewed for approval (aspirin is an example of a "grandfathered" drug). Drugs included in the FDA review process are legend drugs that require a prescription from a doctor, veterinarian or other qualified professional, over-the-counter drugs, and DEA controlled substances.

The FDA new drug approval process encompasses drug selection, preclinical study (chemical characterization, animal testing and screening), clinical study (human testing), long-term toxicity studies of animals, effects on fertility and reproduction, special studies on young animals and other requested studies.

FDA is conducting a review of grandfathered over-the-counter (OTC) drugs to examine their safety and efficacy. More than 300,000 products were classified according to treatment category and active ingredients. Each class is reviewed and monographs produced. Based on these reviews, FDA banned several hundred OTCs in 1990 and 1993. The OTC review is still continuing.

The Washington State Board of Pharmacy

Washington state pharmacies must keep records of the receipt, dispensing and disposition of prescription drugs and controlled substances. Most pharmacies either return the drugs to the wholesaler or manufacturer or use a reverse distributor to manage expired and some unusable drugs.

Pharmaceutical reverse distributors maintain databases of manufacturers' return policies and complete all inventory and paperwork required for the return. In some cases reverse distributors inventory and pack up drugs being returned, in other cases the pharmacist handles this. Pharmacies must keep records of all transactions. The State Board of Pharmacy advises pharmacies to ensure their disposal methods are in compliance with the Washington State Department of Ecology and federal law. Additionally, the State Board of Pharmacy assumes that reverse distributors are in compliance with state environmental laws and with the laws of those states to which drugs are shipped.

The Federal Prescription Drug Marketing Act

To insure that pharmacies continued to stock new product, pharmaceutical manufacturers traditionally offered credit for unusable or expired pharmaceuticals not dispensed by the pharmacy. Prior to passage of the federal Prescription Drug Marketing Act (PDMA) in 1987, manufacturers' representatives either offered credit for expired products or exchanged them for fresh stock at the pharmacy. In some cases outdated or unusable items were returned to a drug wholesaler, which in turn shipped them back to the manufacturer for credit.

The PDMA put restrictions on the return of drugs to manufacturers and, in the case of hospitals, to drug wholesalers. The complexity of returning pharmaceuticals to hundreds of different manufacturers was cost prohibitive for any single pharmacy, and this situation provided an opportunity for entrepreneurs to develop the business model for reverse distribution.
Based on two letters of interpretation (attached)—one to Merck & Co. in 1981, the other to BFI Pharmaceutical Services in 1991—the EPA has allowed unusable or expired pharmaceuticals to flow back through the reverse distribution system as products. While pharmacies ship back unusable or expired pharmaceuticals as 'products' via reverse distributors, the reverse distributor decides whether the items in the shipment are returnable. About 70 percent of a typical shipment is returnable for credit, while the remaining 30 percent will designate as either hazardous or nonhazardous waste (based on RCRA). Of the items being discarded, about 10 percent will typically designate as hazardous waste under RCRA; this is about three percent of the original shipment. The reverse distributor is responsible for properly storing, manifesting, and arranging for transport and disposal of the hazardous waste by a federally permitted RCRA incineration facility. The nonhazardous waste must be disposed of by a facility permitted to destroy nonhazardous pharmaceutical waste.

Reverse distribution is a well-accepted practice and has the approval of the EPA and Ecology. The majority of hospitals, pharmacies and drug wholesalers use this process for expired and unusable pharmaceuticals.

Washington State Departments of Health and Ecology (Radioactive Drugs)
The Nuclear Regulatory Commission delegates authority to the Washington State Department of Health. The Department of Health licenses those involved with radioactive materials including nuclear pharmacies, nuclear medicine, nuclear cardiology, radiopharmaceutical therapies, etc. Additionally, the Department of Health regulates radioactive waste management facilities, low-level radioactive waste disposal, and low-level radioactive waste disposal site users. EPA delegates authority to the Department of Ecology. The Department of Ecology issues site-use permits to users of the commercial low-level radioactive waste disposal site, and regulates mixed waste management. No nuclear or radioactive drugs are included in the proposed exclusion.

When reverse distribution is not an option, how do generators of pharmaceutical waste deal with the dangerous waste regulations?

Most pharmaceutical waste generators are aware of FDA, DEA and Board of Pharmacy regulations and are careful to follow them. In contrast, most small generators of pharmaceutical waste are not aware that they are also regulated by Washington State's Dangerous Waste Regulations (including the requirement to designate wastes to find out if the Dangerous Waste regulations apply.) In fact, for these wastes, designation can be the most burdensome requirement of the Dangerous Waste regulations.

Even though larger generators with dedicated waste management staff are more familiar with the Dangerous Waste regulations, lack of toxicity data and poor oversight and direction from Washington's own waste regulatory agencies have hindered the proper management of their dangerous waste pharmaceuticals. For example, University of Washington waste management staff initially attempted to manage pharmaceutical waste by individually designating each drug wastestream. However, lack of toxicity data and other problems made this task so overwhelming that they abandoned the effort and decided to manage all pharmaceutical waste as dangerous waste. This approach works for the University of Washington because adding a few more wastestreams to the large quantities of dangerous waste generated by the facility does not add much to their disposal costs. However, a smaller operation such as a neighborhood pharmacy would find it cost prohibitive to automatically designate all pharmaceutical waste as dangerous waste and absorb the associated disposal costs.

What pharmaceuticals may designate as RCRA hazardous waste?

See the attached examples compiled by the State of Florida in a fact sheet available on the Internet at http://www.floridacenter.org/brochures_bulletins/rcra_pharmacies.pdf .

What is the nature of pharmaceutical waste?

Expired pharmaceuticals are not waste when returned to a reverse distributor. However, when not returned to a reverse distributor they may become waste.

Expired or unusable pharmaceuticals include those that were originally purchased in a drug store or prescribed by a doctor or veterinarian. Expired pharmaceuticals are those that have exceeded

the FDA expiration date printed on the product or prescription label. They are within the original packaging (boxes, bottles, blister packs, etc.) and still have the manufacturer-provided package inserts.

Unusable pharmaceuticals are those that have been contaminated, adulterated, improperly stored, incorrectly compounded, unlabeled and/or dispensed to a patient and returned. They may be residues or partial doses prepared for administration to a patient in syringes, bags, tubing, cups, etc. or may be drugs that were dropped or spilled and swept off the floor.

Pharmaceutical waste may be liquid or solid (e.g., tablets, capsules, powders, patches or liquid). Although chemotherapy drugs are often managed as dangerous waste because they are perceived to be more toxic, this might not be the case. In one examination of 47 chemotherapy drugs, 18 had insufficient data to designate according to state toxicity criteria, 21 designated WT02 (dangerous waste), and the remaining eight designated WT01 (extremely hazardous waste).

DEA-scheduled drugs are also perceived as having higher toxicity. In a list of 143 scheduled drug (active ingredients only), 80 had insufficient data to designate according to State toxicity criteria, 2 were toxic category B, 35 were toxic category C, and 26 were toxic category D.

For comparison, active ingredients of several well-known prescription and over-the-counter drugs, including Prozac, Viagra, Aleve, Pepto-Bismol, Ritalin and Aspirin, were evaluated for State toxicity criteria. Aluminum hydroxide, fluoxetine hydrochloride (in Prozac), sildenafil citrate (in Viagra), naproxen sodium (in Aleve), bismuth subsalicylate (in Pepto-Bismol) have insufficient data to designate. Aspirin and methyl phenidate (in Ritalin) were toxic category C. Tetracycline, ephedrine, pseudoephedrine, ibuprofen, dimenhydrinate (in Dramamine) were toxic category D. Mangesium hydroxide was not toxic.

As in the examples above, other pharmaceuticals are comparable in toxicity to those already conditionally excluded in the emergency rule, which allows the Spokane Waste-to-Energy facility to accept and incinerate controlled substances as solid waste. The conditional exclusion proposed above incorporates these pharmaceuticals into the final rule along with controlled substances.

Do pharmaceuticals contain mercury?

Regulation of drugs that classify as federally regulated hazardous waste for mercury will not be affected by this rule proposal. Mercury is primarily used as a preservative in drug and biological products. Approximately 200 products (primarily nasal solutions/sprays, ophthalmic solutions/ointments, otic solutions, vaccines, and injectable products) contain mercury. The most common mercury compounds used as a preservative are thimerosal and phenylmercuric acetate.

According to Charlotte Smith of PharmEcology and founder of Capital Returns, a reverse distributor, mercury-containing formulations all designate for the characteristic of toxicity under RCRA and therefore are not a part of the conditional exclusion proposed above.

Does incinerating pharmaceutical waste in a high-temperature combustion unit harm the environment?

No. "Incineration is an appropriate method of disposal for these low volume, low toxicity wastes," as stated in Ecology's Purpose Statement for Emergency Rule WSR-02-04-030, and supported by the workgroup's information on the controls in place at the Spokane Waste-to-Energy facility. Pharmaceuticals that potentially fall under state-only dangerous waste are primarily regulated due to their low toxicity. A few compounds are also halogenated organic compounds and may designate for persistence. The volume of waste pharmaceuticals going to the Spokane Waste-to-Energy facility prior to May 2001 was very low.

Under the proposed language change, how much waste would go to the Spokane Waste-to-Energy facility?

There is no clear data to answer this question. However, it is estimated to be a relatively small amount. According to Damon Taam at the Spokane Regional Solid Waste System, the facility might receive one truckload per year of pharmaceutical waste out of the total 200,000 truckloads of waste going to the incinerator each year. In addition, Spokane Waste-to-Energy facility data indicate that combustion of waste pharmaceuticals has not impacted its air releases. Testing reveals that emission thresholds for all contaminants of concern, including mercury, are far below permitting requirements.

What controls are in place at the Spokane Waste-to-Energy facility to keep contaminants from entering the environment?

The goal of the Waste-to-Energy facility in Spokane is to properly dispose of solid wastes by high temperature combustion. High temperature combustion destroys hazardous products within the solid wastes and as a byproduct generates electricity and an inert ash. The following is a description of how controls at the permitted municipal Waste-to-Energy facility in Spokane keep contaminants from entering the environment, provided by Damon Taam at the Spokane Regional Solid Waste System:

Solid wastes brought to the Waste-to-Energy facility are combusted in the boilers at 2500 degrees F and are kept at this temperature for about 45 minutes. The combustion chamber has very sophisticated combustion control systems that distribute the solid waste evenly to ensure that combustion is complete. The volume of solid waste combusted is reduced by 90 percent, leaving only ferrous metal scrap, glass and ash. The majority of problematic constituents in expired or unusable pharmaceuticals are organic in nature, which are destroyed almost completely through combustion. The combustion in this facility also destroys other hazardous products in the solid wastes, such as PCBs, dioxins and furans.

The Thermal deNOx system injects anhydrous ammonia into the boiler where nitrous oxide (NO) and dioxides (NO2), thought to be precursors to acid rain and components of smog, are broken down into the elements nitrogen and oxygen.

The exhaust gases are rapidly cooled down (critical so that gases cannot recreate dioxins and furans) through heat transfer. At this point powdered activated carbon is injected. The activated carbon enhances the ability of the air pollution control equipment to capture heavy metals and volatile organic chemicals. After the injection of the powdered activated carbon, the exhaust gases are directed to the air pollution control building. Within the air pollution control building the exhaust gases pass through the spray dryer absorber and bag house.

The acid gas scrubber, actually called a spray dryer absorber, is where a lime slurry is injected into a reaction chamber, causing the temperature of the flue gases to drop from 450 to less than 300 degrees F and scrubbing out hydrochloric, sulfuric and hydrofluoric acids. The gas now enters the bag house.

The bag house at the Spokane facility uses 3,420 state-of-the-art fiberglass bags lined with Goretex™ to scrub out fine particulates – small bits of lime, ash or dust that cause air pollution. The stack is monitored for air pollutants continuously and tested thoroughly (to parts per trillion) on a regular basis.

What goes into the Waste-to-Energy facility in Spokane is solid waste – three million tons of garbage since its inception in September 1991 from cities and towns in and around Spokane and beyond. What leaves the Waste-to-Energy facility in Spokane are air emissions equivalent to that of ten EPA-certified wood stoves, ash, scrap metal, and enough electricity to serve about 13,000 homes (about 26 megawatts sold to Puget Sound Power and Light).

What is biohazardous waste and how is it disposed?

Biohazardous waste includes anything contaminated with bodily fluids. A typical “red bag” of biohazardous waste may contain bloody gloves, bandages, sponges, gowns and possibly body parts. A sharps container, also part of biohazardous waste, contains syringes and needles.

Biohazardous waste generated in Washington is generally heat-treated (autoclaved or ‘microwaved’) and disposed as solid waste. The only firm currently permitted to haul biohazardous waste in Washington is Stericycle. Waste handled by Stericycle is sterilized by radiowave, with temperatures reaching 204 degrees F, and then disposed in the solid waste.

The IRAC Pharmaceutical workgroup concludes that the incineration of expired and unusable pharmaceuticals by high-temperature combustion is better than treatment and disposal of pharmaceuticals as biohazardous waste. Neither the radiowave nor autoclave process destroy the shape or activity of the pharmaceutical, whereas incineration destroys both.